

Appl. No. 09/895,027
Reply Dated Sept. 20, 2004
Reply to Office Action of June 20, 2004
Customer No. 27752

REMARKS

Claims 1-21 are pending in the present application and stand rejected. Claim 4 was cancelled in the last response dated March 1, 2004.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO 00/64502 to Krzysik et al. (hereafter "Krzysik"). In support of this rejection, the Office states, in part, that Krzysik teaches "an absorbent article having a liquid impermeable outer surface, a middle absorbent portion and a top liquid permeable bodyside liner facing the wearer." The Office further states that Krzysik teaches that "the bodyside liner may be made of woven or nonwoven materials . . . [and] includes a lotion formulation on the outer bodyfacing surface"

Krzysik discloses an absorbent article having a bodyside liner including a lotion formulation on the outer bodyfacing surface. The lotion formulation comprises from about 5 to about 95 weight percent of an emollient, from about 5 to about 95 weight percent of a wax, and, optionally, from about 0.1 to about 25 weight percent of a viscosity enhancer. The lotion formulation has a reduced level of migration which leads to improved transfer to the skin.

Applicants respectfully submit that the Office has failed to make a *prima facie* case for the obviousness rejections as described below. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. *See In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992); MPEP § 2143.01. Second, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2143.02. Third, the prior art reference or combined references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. Furthermore, in establishing a *prima facie* case of obviousness, case law clearly places the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967).

Claim 1 With regard to Claim 1, the Office concedes that Krzysik "does not teach the claimed thickness of the beneficial components on the porous substrate." The Office goes on to state:

[Krzysik] teaches the lotion can be applied to the bodyside liner at 0.05-100 mg/cm². Accordingly, it would have been within the scope of a skilled artisan to optimize the amounts of lotion applied on the absorbent applied on the article [sic]. The expected result would be a minimum migration of the solidified components applied to the bodyside line [sic].

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Furthermore, the Office argues that Krzysik "states that a z-direction migration loss test shows that the migration of the lotion on the absorbent article is very low."

The Office fails to make a *prima facie* case of obviousness with regard to Claim 1 for several reasons. First, the Office mischaracterizes the limitation present in Applicants' Claim 1. The Office states that Krzysik "does not teach the claimed thickness of the beneficial components on the porous substrate." Applicants make no mention of the "thickness of the beneficial components" in Claim 1. Applicants' limitation is directed to the quantity of beneficial component; more specifically, Applicants' limitation is directed to the quantity of beneficial component present on or within the thickness between 0 and $Z/3$ of the substrate compared to the quantity of the component within the thickness between $2Z/3$ and Z of the substrate until the time of the use of the article. A *prima facie* case of obviousness requires teaching or suggestion of all the claim limitations. The Office has not met its burden to produce a factual basis for its rejection given that Applicants' limitation has been mischaracterized and was not correctly considered by the Office.

Second, the Office argues that since Krzysik teaches that the lotion can be applied at 0.05-100 mg/cm², "it would have been within the scope of a skilled artisan to optimize the amounts of lotion applied on the absorbent article" with the expected result being "a minimum migration of the solidified components applied to the bodyside liner." The Office has failed to present factual support or a convincing line of reasoning in support of this § 103(a) rejection of Applicants' Claim 1. Again, the burden of proof is on the Patent Office to produce a factual basis for its rejection of an application under § 103. See *Warner* at 1016. The Office asserts that optimizing the amount of lotion applied on an absorbent article will produce the expected result of minimum migration of the solidified components to the bodyside liner. The Office provides no factual basis for this "expected result." Does adding more lotion minimize solidified component migration? Does applying less lotion minimize lotion migration? This reasoning posited by the Office is based on mere subjective expectation that is neither convincing nor supported in fact.

Third, Krzysik does not teach or suggest Applicants' claim limitation of a "ratio of the quantity of the beneficial component present on or within the thickness between 0 and $Z/3$ of the substrate is at least about 2.2 times the quantity of the component within the thickness between $2Z/3$ and Z of the substrate until the time of the use of the article." The Office states that since Krzysik teaches a migration loss that is "more desirably [of] no more than 35% . . . it is clear that both the instant invention and WO desire the same result." Applicants dispute that Krzysik provides the same result as claimed by Applicants. Krzysik does not teach Applicants' limitation of a "ratio of the quantity of the beneficial component present on or within the thickness between 0 and $Z/3$ of the substrate is at least about 2.2 times the quantity of the component within the

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thickness between $2Z/3$ and Z of the substrate until the time of the use of the article." Therefore, the Office's assertion that "the instant invention and WO desire the same result" lacks support from the Krzysik document.

In further regard to this third point, the Office continues to equate the Z-Direction Lotion Migration Test disclosed in Krzysik (*see* page 21-22) as equivalent to Applicants' method for determining the top-bias ratio (*see* page 21, lines 12 to page 23, line 13). The Krzysik test and Applicants' test are distinct and measure differing properties of the substrate bearing the beneficial component. Case law states, "To evaluate obviousness, a comparison must be made between the prior art as a whole and the claimed subject matter as a whole." *In re Langer and Haynes*, 465 F.2d 896 (CCPA 1972). With this law in mind, Applicants direct the Office's attention to the Krzysik test. The test is "a measure of the lotion migration after [article] storage at 130°F when compared to the lotion migration at 73°F after a fixed period of time." *See* page 21, lines 11-13. The test is described in detail on pages 21-22 of the present specification. It involves subjecting a sample of the bodyside liner to Soxhlet Extration whereby "chloroform dissolves the lotion from the liner sample." The chloroform/lotion mixture returns to the reboiler. The reboiler is controlled to vaporize the chloroform but not the lotion. Krzysik clearly states that the "chloroform dissolves the lotion from the liner sample." Applicants assert that the chloroform dissolves the lotion regardless of its location whether on the bodyfacing side of the liner, on the opposite side of the liner, or within the liner. The resulting measurement is of the total amount of lotion present on and within the sample. Since Krzysik cannot even determine the concentration of lotion in or on the liner, it is abundantly clear that the Krzysik test cannot determine the lotion concentration present in three thicknesses of the sample between $0 - 1/3Z$, $1/3Z - 2/3Z$, or $2/3Z - Z$, when Z is the measured thickness of the sample.

The Office's reliance on the Krzysik Z-Direction Lotion Migration Test is further misplaced because while the title of the test is "Z-Direction Lotion Migration Test," it is clear that lotion may migrate in other directions. Krzysik states that the test predicts "how quickly [the lotion] will undesirably migrate away from or along the body facing surface of the article in use." Movement away from or along the body facing surface indicates that lotion is migrating in directions other than or in addition to through the thickness of the liner in Krzysik.

Upon closer inspection of the Krzysik test, the Office should find that (i) any assertion that the Krzysik test teaches or suggests Applicants' top-bias ratio is unsupported in fact, (ii) the Krzysik test cannot affirmatively determine if migratory loss of lotion is a result of migration through the thickness of the liner, and (iii) the Krzysik test cannot determine lotion concentration on or within discrete thicknesses of the liner. As a result of these findings, the Office has again

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failed to meet its burden of providing a factual basis for the rejection; this rejection is based on misapplication of the Krzysik test.

Fourth, Krzysik does not teach or suggest Applicants' limitation within Claim 1 wherein "the beneficial component comprises at least a first layer and second layer." The Office makes the following assumptions:

[I]nstant claim 1 only states first and second layer, but does not require that the two layers be different. Therefore, if the [sic] both layers are to contain the same beneficial component, the process of layering the beneficial component only results in mixing up the components and the layers do not remain distinct.

[I]nstant specification states (page 16) that the hydrophilicity and hydrophobicity of the first and second layers is not critical.

[A]pplicants have not shown any unexpected results with the beneficial component being in the form of layers as opposed to being applied as a single composition.

See page 5 of the Office Action dated June 20, 2004. Based upon these assumptions, the Office concludes that "incorporating the beneficial component on the article as a single (layer) component or as different layers by routine optimization would be within the gambit of a skilled artisan." Both the Office's assumptions and conclusion of "routine optimization" are unsupported and/or without merit.

Applicants assert that the Office's conclusion that incorporating the beneficial component as layers would be within the gambit of a skilled artisan does not follow from the assumptions made. The first assumption suggests a process and is not directed to the claim as written. The second assumption suggests that the relative hydrophilicity or hydrophobicity of the layers is not critical. The third assumption relates to the unexpected results achieved by the layers. Assuming *arguendo* that the Office's assumptions are correct (which Applicants clearly refute below), there is still no motivation to modify Krzysik to provide for layering of the lotion. In fact, according to the Office's first assumption, there would be no motivation to layer beneficial components if, as according to the Office, "layering the beneficial component only results in mixing up the component." The assumptions posited by the Office do not lend support to the Office's conclusion that "incorporating the beneficial component on the article as a single (layer) component or as different layers by routine optimization would be within the gambit of a skilled artisan." Instead, the statement is merely conclusory and is absent factual support or a convincing line of reasoning. Applicants will next examine the Office's assumptions.

Initially, Applicants wish to point out that the Office has not pointed to any passage within Krzysik that teaches or suggests two layers of beneficial component. The Office's support for the assertion (i.e., "incorporating the beneficial component on the article as a single (layer)

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component or as different layers by routine optimization would be within the gambit of a skilled artisan") appears to be based solely upon reference to Applicants' disclosure. Case law has held that the teaching or suggestion to modify the prior art must be found in the prior art and not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Such reference to Applicants' disclosure in support of an obviousness rejection suggests impermissible hindsight.

Applicants agree that Claim 1 as presented does not require that the two layers be different. However, Applicants fail to see how the Office's assumption (i.e., "the process of layering the beneficial components only results in mixing up the components") teaches Applicants' limitation of an article comprising, in part, a beneficial component comprising a first layer and a second layer. The Office's assumption is directed to a process which does not address the limitation of an article. The assumed result achieved from this hypothetical layering process is immaterial. The Office still has not pointed something in the prior art that teaches or suggests Applicants' recited limitation. Krzysik clearly does not teach or suggest a first and second layer of its lotion. The Office has not presented another reference or a convincing line of reasoning to teach or suggest this limitation. As a result, the Office has not met its burden to produce a factual basis for the rejection.

The Office states that the "instant specification states (page 16) that the hydrophilicity and hydrophobicity of the first and second layers is not critical." The Office has selectively read and overstated Applicants' disclosure. Applicants, on page 16, lines 24-32 recite various embodiments of the present invention. One embodiment teaches the two layers as differing in hydrophilicity or hydrophobicity. In another embodiment, the relative hydrophilicity or relative hydrophobicity is not critical. Another embodiment speaks to a layer being a volatile base layer. Applicants have merely stated that in some embodiments the relative hydrophilicity or relative hydrophobicity of the layers are not critical; however, in other embodiments, the relative hydrophilicity or relative hydrophobicity may be critical. The Office's sweeping statement that the "instant specification states (page 16) that the hydrophilicity and hydrophobicity of the first and second layers is not critical" is overly broad and misleading.

The Office states that "applicants have not shown any unexpected results with the beneficial component being in the form of layers as opposed to being applied as a single composition." To the contrary, the Office is directed to page 21, line 23 to page 23, line 13 of the specification. Three conditions are provided in the chart on page 23 along with the resulting top-bias ratio. Condition "i" represents a single layer of just lotion. Condition "ii" represents two layers, water/glycerine and lotion. Condition "iii" represents three layers; water/glycerine, lotion, and water. The top-bias ratios for conditions i, ii, and iii are 2.1:1, 2.9:1, and 3.7:1, respectively. These results show the unexpected result of an increased top-bias ratio where a beneficial

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component comprises a first and second layer. The Office's assertion that Applicants "have not shown any unexpected results" is inaccurate given that ample support exists within the present specification showing the results.

Claim 5 With regard to Claim 5, the Office mischaracterizes Applicants' disclosure. The Office states that "applicants themselves state that the relative hydrophilicity or relative hydrophilicity is not critical. Accordingly, if the two layers have [sic] same hydrophobicity or hydrophilicity to each other, the resulting beneficial component applied on the substrate would be the same as that of the WO." Applicants have shown above that in some embodiments the relative hydrophilicity or relative hydrophobicity of the layers is not critical; however, in other embodiments, the relative hydrophilicity or relative hydrophobicity may be critical. Claim 5 is clearly directed to one layer being relatively hydrophilic and one layer being relatively hydrophobic. Again, the Office appears to be using Applicants' disclosure as the basis for the rejection rather than pointing to some teaching in the prior art; this suggests improper hindsight reconstruction.

Furthermore, Krzysik teaches away from Applicants' claim limitation of relatively hydrophilic and relatively hydrophobic layers. Krzysik teaches that its lotion formulation is prepared by "mixing until all ingredients were melted and uniform." Krzysik's teaching of uniformity of the ingredients, both hydrophilic and hydrophobic ingredients, is in direct contradistinction to Applicants' claimed layers. If Krzysik's composition is uniform (i.e., both hydrophilic and hydrophobic ingredients are mixed together), the Office cannot read Krzysik as teaching a hydrophilic layer and a hydrophobic layer. As such, the Office has failed to consider Krzysik as a whole and appreciate the clear teaching away from Applicants' claimed invention that exists therein.

Additionally, there is no motivation to modify the article of Krzysik so as to yield Applicants' claimed invention. While Krzysik may teach hydrophilic and hydrophobic ingredients for the lotion formulation, Applicants claim relatively hydrophilic and relatively hydrophobic layers. Krzysik does disclose that its lotion formulation may be applied as stripes. See page 19, line 32. However, Applicants fail to see the factual support for the Office's conclusion that Krzysik's lotion deposition pattern of stripes suggests that the lotion may be applied in layers, wherein one layer is relatively hydrophobic and one layer is relatively hydrophilic. The Office has failed in its initial burden to factually support the *prima facie* case of obviousness.

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Claim 9 and 16 With regard to Claims 9 and 16, the Office concedes two points in that Krzysik "does not explicitly teach layers of beneficial component or disposing a first or disposing a first hydrophilic layer followed by a hydrophobic layer." However, the Offices states that Krzysik teaches or suggests the following four points:

[L]imiting the lotion to restricted areas of the article such that migration to the interior or lateral migration of [sic] the absorbent body is not observed.

[A]pplying the lotions to discreet [sic] areas as stripes as [sic] full length or a portion of the article and further in an add-on level, including the claimed steps of applying the component and solidifying.

[D]eposition of wax, emollients, and other viscosity enhancers such as celluloses, silica, petrolatum, aloe etc., [sic] all of which read on instant hydrophilic components, along with emollients and wax (hydrophobic) in the lotion formulation.

[T]he lotion formulations be applied to the entire body face or may be applied selectively to particular sections, so as to provide greater lubricity to such sections and can be applied in stripes.

See page 3 of the Office Action dated June 20, 2004. The Office then concludes that "it would have been obvious for one of ordinary skill in the art at the time of the instant invention to apply the lotion composition in a desired thickness or amounts with an expectation to exhibit minimum migration." The Office does not address the claims as presented. Applicants traverse the rejection.

Claim 9 is an article with a beneficial composition that "comprises a first layer and a second layer and wherein (a) the first layer is disposed on the contacting surface; (b) the second layer is disposed on the first layer" None of the four points the Office provides in support of the conclusion teaches or suggests all of the limitations recited in Claim 9. Furthermore, the Office's conclusion does not even address Claim 9. The Office concludes that Krzysik teaches or suggests "minimum migration"; however, the claim limitation is directed to a structure that is not taught or suggested by Krzysik. As a result, the Office has failed in its *prima facie* case of obviousness.

In further regard to Claim 9, the Office has failed to present a convincing line of reasoning for asserting that Krzysik's deposition pattern of stripes suggests that the lotion maybe applied in layers. The Office's assertion that applying beneficial agents in discrete patterns such as layer would have been within the scope of a skilled artisan is factually unsupported and purely conclusory. The Office has failed in its initial burden to factually support the *prima facie* case of obviousness.

Claim 16 is directed to the method for top-biasing a composition on a porous substrate comprising the steps of applying a first layer of a relatively hydrophobic component, applying a

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second layer of a relatively hydrophobic component; and allowing the first and second layers to simultaneously cool without formation of an emulsion. The Office offers that the same reasoning as presented with respect to Claim 9 is equally applicable to Claim 16. The Office presents four points from Krzysik, but these points neither teach nor suggest Applicants' presently claimed method. The Office concludes that Krzysik teaches or suggests "minimum migration"; however, the claim limitation is directed to a method comprising three steps that are not taught or suggested by Krzysik. As a result, the Office has failed in its *prima facie* case of obviousness.

In further regard to Claim 16, Krzysik teaches away from Applicants' claimed invention. Krzysik clearly discloses "uniformly applying the melted formulation to the bodyfacing surface of the bodyside liner." Applicants' claim recites, in part, a method of applying a first layer of a relatively hydrophilic component and applying a second layer of a relatively hydrophobic component. Krzysik clearly requires uniform application of the lotion formulation which is in sharp contrast to Applicants' claimed layered method. When the claimed method involves doing what the cited reference tries to avoid, "[t]his is the very antithesis of obviousness." *In re Buehler*, 515 F.2d 1134, 1141 (CCPA 1975).

Additionally, there is no motivation to modify the article of Krzysik so as to yield Applicants' claimed invention. While Krzysik may teach hydrophilic and hydrophobic ingredients for the lotion formulation, Applicants claim applying a first layer of a relatively hydrophilic component and applying a second layer of a relatively hydrophobic component. While Krzysik discloses that its lotion formulation may be applied as stripes, the Office has failed to present a convincing line of reasoning for asserting that Krzysik's deposition pattern of stripes suggests Applicants' method for applying a first layer of a relatively hydrophilic component and applying a second layer of a relatively hydrophobic component. Applicants have found no teaching or suggestion that the Krzysik lotion formulation involves application of multiple layers. The Office's obviousness rejection remains unsupported in fact or by a convincing line of reasoning.

The Office remarks, presumably with regard to Claims 9 and 16, that "adding the beneficial agents, hydrophobic or hydrophilic or both, in discreet [sic] patterns such as layers or stripes etc., and allowing the component to result in a proper composition, such emulsion formation or suspension or solution without affecting the optimum migration of the beneficial components would have been within the scope of a skilled artisan." Regardless to which claim, either 9 or 16, this remark is directed, it is meretricious. Claim 9 recites a beneficial composition that "comprises a first layer and a second layer." Krzysik does not teach or suggest a first layer and a second layer. The Office continues to suggest that a stripe, as disclosed by Krzysik, is analogous to a first and second layer. Applicants respectfully request that the Office distinctly

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point out where within Krzysik a first layer and a second layer are taught. Merely stating that a particular limitation is "within the scope of a skilled artisan" is conclusory and unsupported in fact. Claim 16 recites a method. Krzysik does not teach or suggest each of the steps of the claimed method.

With regard to dependent claims not specifically addressed above, Applicants submit that all independent claims have been traversed. As such, all dependent claims depending therefrom and containing all limitations are also nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988)

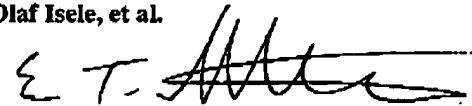
CONCLUSION

All rejections in the Office Action have been addressed. Based on the foregoing reasons, Applicants respectfully request reconsideration and allowance of each of the pending claims.

Respectfully Submitted,

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